

In re Application of: Michal DANIELY et al  
Serial No.: 10/771,440  
Filed: February 5, 2004  
Final Office Action Mailing Date: December 11, 2008

Examiner: Bradley DUFFY  
Group Art Unit: 1643  
Attorney Docket: 26003

### **REMARKS**

Reconsideration of the above-identified Application in view of the amendments above and the remarks following is respectfully requested.

Claims 37, 39, 40, 54, 55, 57, 72 and 73 are in this Application. Claims 37, 39, 40, 54-55, 57 and 72-73 have been rejected under 35 U.S.C. §112. Claims 37, 39, 40, 55, 57, 72 and 73 have been rejected under 35 U.S.C. §102. Claims 37 and 54 have been rejected under 35 U.S.C. §103. Claims 72 and 73 have been amended herewith. Claims 37, 39, 40, 54, 55 and 57 have been cancelled herewith. New claims 82-86 have been added herewith.

In a telephone interview graciously granted by Examiner Bradley Duffy and Supervisor Stephen Rawlings held on March 11, 2009, the following issues were discussed.

Applicants' representative stated that the suggested claim amendments which now expressly require, as an active step, the identification of a single cell having a morphological abnormality associated with transitional cell carcinoma and the identification of a chromosomal abnormality associated with said transitional cell carcinoma in the same single cell should overcome the 102(b) rejections.

In addition, Applicants' representative stated such claim amendments, which now recite "the same said single cell" should overcome the 112 rejections.

With respect to the 112 rejections, Examiner stated that the suggested amendments would seem to overcome rejections.

With respect to the 102 (b) rejections, the Examiner stated that he would require further considerations. Examiner agreed that the 103(a) rejections were rendered moot in view of cancellation of claims pertaining to same.

### **Information Disclosure Statement (IDS)**

In response to the Examiner's comment on page 2 of the Final Office Action respecting a reference previously disclosed and considered but crossed out because its date of publication was not included, Applicants herewith submit an additional Information Disclosure Statement (IDS) listing said reference with its full and correct citation including its date of publication, thereby complying with MPEP §609.

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The Examiner is requested to make this citation of official record in this Application.

### 35 U.S.C. §102 Rejections

Grounds of rejections maintained: The Examiner has maintained his rejections to claims 37, 39, 40, 55, 57 and 72-73 under 35 U.S.C. §102(b) as being anticipated by Skacel et al. (2001). Specifically, the Examiner states that the claims have been amended to recite that the staining steps have the intent "*so as to identify a single cell having a morphological abnormality associated with transitional cell carcinoma*" and "*so as to identify a chromosomal abnormality associated with said transitional cell carcinoma in said single cell*", but they do not expressly limit the recited process to identifying in the same single cell both a morphological abnormality and a chromosomal abnormality. The Examiner states that the instant claims broadly, but reasonably encompass imaging different single cells for morphological abnormalities and chromosomal abnormalities as taught by Skacel, and therefore maintains his rejections. Examiner's rejections are respectfully traversed. Claims 37, 39, 40, 54, 55 and 57 have been cancelled herewith, thereby rendering moot Examiner's rejections with respect to these claims. Claims 72 and 73 have now been amended. New claims 82-86 have been added.

In order to expedite prosecution of this case, Applicants have amended claim 72 to recite:

*"72. A method of identifying transitional cell carcinoma cells in a urine sample comprising:*

*(a) staining nucleated cells of the urine sample using a stain selected from the group consisting of May-Grünwald-Giemsa, Giemsa, Papanicolaou and Hematoxylin-Eosin to thereby obtain stained nucleated cells, and subsequently;*

*(b) imaging said stained nucleated cells resultant of step (a) so as to obtain images of said stained nucleated cells, and subsequently;*

*(c) identifying in said images of step (b) a single cell having a morphological abnormality associated with transitional cell carcinoma, and subsequently;*

*(d) staining said stained nucleated cells resultant of step (a) using fluorescent in situ hybridization (FISH) to thereby obtain nucleated cells stained with FISH, and subsequently;*

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*(e) imaging said nucleated cells stained with FISH resultant of step (d) so as to obtain images of said nucleated cells stained with FISH, and subsequently;*

*(f) identifying in said images of step (e) a chromosomal abnormality associated with said transitional cell carcinoma in the same said single cell identified in step (c) having said morphological abnormality associated with transitional cell carcinoma;*

*wherein presence of said morphological abnormality and said chromosomal abnormality in the same said single cell indicates that said same single cell is a cancerous cell*

*thereby identifying the transitional cell carcinoma cells in the urine sample.” (Emphasis added) to thereby overcome Examiner’s rejections.*

Claim 73 has been amended accordingly.

Applicants point that as acknowledged by Examiner (Final Official Action dated December 11, 2008, Page 5, last paragraph, and Page 6, first paragraph) the cells shown in Figures 2A and 2B of Skacel et al. are not the same exact cells, therefore Skacel et al., could not anticipate the invention as now claimed which expressly require, as an active step, the identification of a single cell having a morphological abnormality associated with transitional cell carcinoma and the identification of a chromosomal abnormality associated with said transitional cell carcinoma in the same single cell.

Support for the amendments can be found in Page 27 (from line 27) through Page 28 (line 7) in the instant Application as filed.

In view of the above claim amendments and remarks Applicants believe to have overcome the 35 U.S.C. §102(b), rejections.

### **35 U.S.C. §103 Rejections**

**Grounds of rejections maintained:** The Examiner has maintained his rejections to claims 37 and 54 under 35 U.S.C. §103(a) as being unpatentable over Skacel et al., in view of US Patent No. 6,418,236.

In view of cancellations of claims 37 and 54, Examiner’s rejections under 35 U.S.C. §103 are rendered moot.

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**35 U.S.C. §112 Rejections**

**New Grounds of Rejections**

The Examiner has rejected claims 37, 39-40, 54-55, 57 and 72-73 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner states that the recitation of “identifying in said images said single cell having said morphological abnormality and said chromosomal abnormality in claims 37, 55, 72 and 73 renders the claims indefinite because the claimed processes recite imaging a plurality of stained nucleated cells, *i.e.*, a plurality of single cells, so it is unclear, which “*single cell*” is necessarily identified. Examiner’s rejections are respectfully traversed. Claims 37, 39-40, 54-55 and 57 have been cancelled herewith. Claims 72 and 73 have been amended herewith.

Applicants point out that the amendments made in response to the 102(b) rejections to recite “*the same said single cell*” overcome Examiners rejections under 35 U.S.C. §112, second paragraph.

In view of the claim amendments Applicants believe to have overcome the 35 U.S.C. §112, rejections.

In view of the above amendments and remarks it is respectfully submitted that amended claims 72 and 73, and new claims 82-86 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,



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Registration No. 40,338

Date: April 6, 2009

**Enclosures:**

- Request for Continued Examination (RCE);
- Petition for Extension of Time (One Month); and
- Corrected Information Disclosure Statement (IDS)